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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,676	10/31/2003	Martin T. Gerber	P-11666.00US	1023

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MEDTRONIC, INC.
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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,676

Applicant(s)

GERBER ET AL.

Examiner

Matthew J. Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


BEVERLY M. PLANAGAN
PRIMARY EXAMINER

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/31/03.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claim Objections

Claim 12 is objected to because of the following informalities: Line 4 of claim 12 wherein "a needle positioned through the hole of the" is incomplete.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 12-20 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,231,591 to Desai.

In regards to claims 12, 24 and 26, Desai discloses a system for delivering a denervating agent to a prostate gland comprising: an imaging apparatus 304 sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole; a needle positioned through the hole of the for insertion through a rectal wall of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen (see Col. 19, Line 67 - Col. 20, Line 11 and Fig. 25).

In regards to claims 13-14 and 25, Desai discloses a system for delivering a denervating agent to a prostate gland, further comprising a spring mechanism and an actuator 338 to bias the needle into the prostate gland upon actuation (see Col. 19, Lines 31-32 and Fig. 25).

In regards to claim 15, Desai discloses a system for delivering a denervating agent to a prostate gland, further comprising a denervating agent delivery 348 assembly coupled to the needle to deliver the denervating agent through the lumen (see Col. 17, Lines 18-57).

In regards to claims 16-18, Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery system assembly 348 includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen. As can be seen in Fig. 25 the second actuator comprises a plunger as well as a hub and a fluid line for attachment of the reservoir to the needle (see Col. 17, Lines 53-55).

In regards to claims 19-20, Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery assembly 348 includes a first reservoir to hold a substantial amount of the denervating agent, a second reservoir to hold a discrete dose of the denervating agent, and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator (see col. 20, Lines 51-65, and Col. 21, Lines 18-30).

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Syringe 348 is interpreted to be the first reservoir and the lumen of needle 306 is interpreted to be the second reservoir.

In regards to claims 22-23, Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the imaging apparatus comprises an ultrasonic imaging apparatus and is inherently capable of comprising a hyper-echoic coating as is well-known in the art (see Col. 19, Lines 64-67).

In regards to claims 1, 3-8 and 10, the apparatus of Desai is considered to be inherently capable of performing the recited method claims. Furthermore, Desai discloses a method of localized fluid therapy (see Col. 19, line 57 – Col. 20, Line 51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 9, 11 and 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 6,365,164 to Schmidt.

In regards to claim 21, Desai discloses a system for delivering a denervating agent to a prostate gland but is silent with respect to the denervating agent including botulinum toxin. Schmidt teaches methods for treating neuronally-mediated urologic and related disorders and more particularly, benign

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prostatic hyperplasia (BPH), by administering a composition that includes at least one neurotoxic compound. Such a neurotoxin can be botulinum toxin type A (see Col. 4, Lines 3-29). It would have been obvious to one skilled in the art at the time the invention was made to use a composition including botulinum toxin type A with the device of Desai in order to help more effectively treat BPH as taught by Schmidt.

In regards to claims 2, 9 and 11, the apparatus of Desai and Schmidt is considered to be inherently capable of performing the recited method claims. Furthermore, Schmidt discloses that dosing can be singular or cumulative and can be readily determined by one skilled in the art (see Col. 4, Lines 36-60).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,234,004 to Hascoet et al.

U.S. Patent No. 5,542,915 to Edwards et al.

U.S. Patent No. 6,692,490 to Edwards

U.S. Patent No. 5,599,294 to Edwards et al.

U.S. Patent Application Publication No. 2004/0015051 to Sudakov et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK

6/8/05


BEVERLY M. FLANAGAN
PRIMARY EXAMINER